



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
--------------------	-------------	-----------------------	---------------------

08/409,122 03/22/95 JOYCE

J 19425

CHEN, H EXAMINER

18M1/0923

CHRISTINE E CARTY
PATENT DEPT
MERCK AND CO INC
P O BOX 2000
RAHWAY NJ 07065-0907

ART UNIT PAPER NUMBER

1813
DATE MAILED:

09/23/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 5/15/95, 11/6/95

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-12 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 3

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

* ☒ Notice to comply with requirements for nucleotide sequence and/or amino acid sequence
- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

Art Unit: 1813

DETAILED ACTION

1. This application fails to comply with the requirements of 37 CRF 1.821-1.825. A notice to comply with requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures is attached.

2. Claims 1,2, 4-6, 8-11 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rose et al (1994).

Rose teaches a method of producing HPV capsid protein and virus-like particle consisting HPV 18 in a baculovirus expression system. Rose also suggests that other host cell for expression of the capsid protein include yeast cell. (see page 10, lines 18-28). A virus-like particle produced from the capsid protein of papillomavirus, wherein said particle comprises antigenic characteristics similar to those of native infectious papillomavirus particles. Although a virus-like particle produced from the capsid protein of papillomavirus in yeast cell may contain minor modification, wherein said particle is similar to those produced from insect cell. Rose further teaches the production and purification of the virus-like particles by CsCl or salt fractionation method, the same procedures as instant claims. Therefore, claims 1, 2, 4, 8-9, 11 are anticipated or obvious over the teachings of Rose.

Rose suggests that the virus-like particles can be used for vaccine development, both therapeutic and prophylactic (see page 6, line 15-18). Therefore, claims 5-6 and 10 are obvious over the teachings of Rose.

Art Unit: 1813

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8-9, 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowy et al (1992) and Rose et al (1994).

Lowy teaches a method of producing the recombinant HPV 16 capsid proteins in a host cell, and wherein host cell is a insect cell, yeast cell or mammalian cell. Lowy further teaches the procedures of purification of recombinant capsid proteins by CsCl or salt fractionation, the same method as instant application. Lowy does not use HPV18 as starting material to produce recombinant capsid proteins. Rose teaches a method of producing HPV 18 recombinant capsid proteins in a yeast cell. It would have been obvious to one of ordinary skill in the art at the time of invention to produce recombinant HPV 18 capsid proteins by using starting material HPV 18 DNA of Rose and the method of producing recombinant capsid proteins in yeast according to the teachings of Lowy with the reasonable expectation that the change of starting material would result in the production and purification of HPV 18 recombinant capsid proteins. Absent any showing of unexpected result, the invention as claimed was prima facie obvious to one of ordinary skill in the art at the time of the invention.

4. Claims 5-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowy et al and Rose et al as applied to claims 1-4, 8-9 and 11-12 above, and further in view of Lowy et al.

Art Unit: 1813

(1992) and Rose et al (1994). Lowy further teaches that the recombinant capsid proteins of HPV can be used for vaccine development, and wherein said vaccine can be used for preventing or treating or immunizing a vertebrate against papillomavirus infection. Rose also suggests that VLPs can be used for vaccine development, both therapeutic and prophylactic. One of ordinary skill would have expected to use HPV 18 as starting material to produce recombinant capsid proteins and use for vaccine development, wherein said vaccine can be used for preventing or treating or immunizing an animal against papillomavirus infection. Therefore, the invention as whole would have been prima facie obvious to one of ordinary skill in the art at the time of invention was made.

5. Claim 4 is rejected under 35 U.S.C. 101 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 2 be found allowable, claim 4 will be rejected under 35 U.S.C. 101 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Chen whose telephone number is (703) 305-2222.

Serial Number: 08/409,122

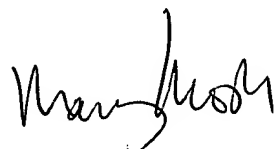
Page 5

Art Unit: 1813

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christine Nucker can be reached at (703)308-4028. Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703)308-0196. Papers related to this application may be submitted to group 180 by facsimile transmission at (703)305-7939.

Michael Chen, Ph.D.

Sept. 5, 1996


**MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800**